

Clindasol-T^{Gel}

(Clindamycin Phosphate + Tretinoin)

COMPOSITION

Each gram contains:

Clindamycin phosphate12mg

Tretinoin0.25mg

(Innovator's specifications)

DESCRIPTION

Clindasol-T Gel (clindamycin phosphate and tretinoin), 1.2%/0.025%, is a fixed combination of two solubilized active ingredients in an aqueous based gel. Clindamycin phosphate is a water soluble ester of the semi-synthetic antibiotic produced by a 7(S)-chlorosubstitution of the 7(R)-hydroxyl group of the parent antibiotic lincomycin. Tretinoin is a member of the retinoid family of compounds. This combination is helpful in the topical treatment of acne vulgaris.

MECHANISM OF ACTION

Clindamycin

The mechanism through which topical clindamycin treats acne vulgaris is unclear, but may be related to its activity against Propionibacterium acnes, a bacteria that has been associated with acne.

Tretinoin

Although the exact mode of action of tretinoin is unknown, current evidence suggests that topical tretinoin decreases cohesiveness of follicular epithelial cells with decreased microcomedone formation. Additionally, tretinoin stimulates mitotic activity and increased turnover of follicular epithelial cells causing extrusion of the comedones.

INDICATIONS

Clindasol-T gel is indicated for the topical treatment of acne vulgaris in patients 12 years or older.

DOSAGE & ADMINISTRATION

Clindasol-T gel should be applied once daily in the evening, gently rubbing the medication to lightly cover the entire affected area. Approximately a pea sized amount will be needed for each application. Avoid the eyes, lips,

and mucous membranes.

Clindasol-T gel is not for oral, ophthalmic, or intravaginal use.

Instructions for Use

- At bedtime, the face should be gently washed with mild soap and water. After patting the skin dry, apply Clindasol-T gel as a thin layer over the entire affected area (excluding the eyes and lips).
- Patients should be advised not to use more than a pea sized amount to cover the face and not to apply more often than once daily (at bedtime) as this will not make for faster results and may increase irritation.
- A sunscreen should be applied every morning and reapplied over the course of the day as needed. Patients should be advised to avoid exposure to sunlight, sunlamp, ultraviolet light, and other medicines that may increase sensitivity to sunlight. Other topical products with a strong drying effect, such as abrasive soaps or cleansers, may cause an increase in skin irritation with Clindasol-T gel.

PHARMACOKINETICS

Clindamycin

Clindamycin is converted within the skin by phosphatases leading to the more potent form of clindamycin. Thus, conversion to clindamycin is a major determinant of antimicrobial activity in the skin layers following topical application of clindamycin phosphate.

Tretinoin

Tretinoin occurs in the body as a metabolite of retinol, and it exhibits a certain degree of Vitamin A growth-promoting activity. Representative well-controlled clinical studies conclude that topically applied tretinoin does not increase plasma all trans retinoic acid (tretinoin). Following a single topical application of radiolabeled tretinoin, the blood concentration of retinoic acid was found to be unchanged from 2-48 hours. Neither single-dose nor long-term treatment with topical tretinoin formulations does alter systemic retinoid levels, which remain within the range of body's natural endogenous levels.

PRECAUTIONS

- Clindasol-T is not for oral, ophthalmic, intranasal or intravaginal use.
- Contact with the mouth, eyes and mucous membranes and with abraded or eczematous skin should be avoided. Application to sensitive areas of skin should be made with caution. In the event of accidental contact with the eyes, bathe with large amounts of water.
- Antibiotic-associated colitis (also known as Clostridium difficile-associated colitis or CDAD) has been reported with the use of some other topical clindamycin products. This is unlikely to occur with Clindasol-T, as plasma levels have been determined and the percutaneous absorption of clindamycin is clinically negligible.
- If prolonged or significant diarrhoea occurs or the patient suffers from abdominal cramps, treatment with Clindasol-T should be discontinued immediately, as the symptoms may indicate antibiotic-associated colitis. Suitable diagnostic methods, such as the determination of Clostridium difficile and toxin and, if necessary, colonoscopy should be employed and treatment options for colitis considered.
- Use of more than the recommended amount or too frequent application may cause redness, stinging and discomfort. If severe irritation occurs, especially in the early stage of therapy, patient should be advised to discontinue temporarily or reduce the frequency of application.
- Clindasol-T should be prescribed with caution in atopic subjects.
- Clindasol-T should not be applied at the same time as other topical preparations (including cosmetics) because of possible incompatibility and interaction with tretinoin. Particular caution should be exercised in the use of keratolytic agents such as sulphur, salicylic acid, benzoyl peroxide or resorcinol and chemical abrasives. If the patient has been treated with such preparations, the effect of the peeling agents must subside before any commencement of Clindasol-T therapy.
- Some medicated cleansers and scrubbing solutions have a strong drying effect. They should not be used in patients receiving tretinoin topical therapy. Abrasive soaps, soaps and cosmetics as well as spices or lime should be used with caution.
- Because of increased susceptibility to UV radiation, photosensitivity may occur during treatment with Clindasol-T gel. Exposure to sunlight should therefore be minimized and appropriate sunscreen products with

a SPF (Sun Protection Factor) of at least 30, together with suitable protective apparel (e.g. a hat), should be used. Use of sun lamps or sun beds should be avoided during treatment and patients with sunburn should not use this product until recovered.

Patients who may be required to have considerable sun exposure due to occupation and those with inherent sensitivity to the sun should exercise particular caution. If sunburn occurs, discontinue therapy with Clindasol-T until the severe erythema and peeling subside.

Occasional gram-negative folliculitis has been reported during treatment with clindamycin 1% topical products. If this should occur, therapy with Clindasol-T should be discontinued and alternative therapy should be initiated.

Long-term use of clindamycin may cause resistance and/or overgrowth of non-susceptible dermal bacteria or fungi although this is a rare occurrence. Cross resistance may occur with other antibiotics such as lincomycin or erythromycin.

Simultaneous use of oral and topical antibiotics should be avoided, particularly if chemically different.

Pregnancy

Pregnancy Category C. There are no well-controlled studies in pregnant women treated with Clindasol-T gel. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

It is not known whether clindamycin is excreted in human milk following use of Clindasol-T gel. However, orally and parenterally administered clindamycin has been reported to appear in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. It is not known whether tretinoin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Clindasol-T gel is administered to a nursing woman.

SIDE EFFECTS

Hypersensitivity, Eye irritation, Dermatitis, macular rash, skin bleeding, skin burning sensation, skin depigmentation, skin irritation, Application site reaction, application site burning, application site pruritus, application site exfoliation, application site dermatitis, application site dryness, and application site erythema.

خوراک و طریقہ استعمال:

روزانہ ایک دفعہ رات سوئے سے پہلے منہ کے دانے کے برابر جل لے کر منہ کا تھوڑا حصہ پر لگانا ہے۔ آنکھوں، منہ، ناک کے اندر وونی حصوں اور نازک جلد پر نہ لگانا ہے۔ یا ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۲۵ ڈگری سینٹی گریڈ سے کم درجہ پر رکھیں۔ دھوپ، گرمی، نمی اور نمند ہونے سے بچائیں۔ تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔ صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔ صرف بیرونی استعمال کے لئے۔

DRUG INTERACTIONS

- Concomitant topical medication as well as medicated soaps and cleansers that have a strong drying effect and products with high concentrations of alcohol as well as astringents should be used with caution.
- The concomitant treatment with corticosteroids should be avoided.
- In vitro, antagonism has been demonstrated between erythromycin and clindamycin, synergy has been shown with metronidazole, both antagonistic and synergistic effects have been observed with aminoglycosides and agonistic action has been described with neuromuscular blocking agents.
- Increased coagulation tests (PT/INR) and/or bleeding, have been reported in patients treated with clindamycin in combination with a vitamin K antagonist (e.g. warfarin, acenocoumarol and fluidione). Coagulation tests, therefore, should be frequently monitored in patients treated with vitamin K antagonists.
- Tretinoin causes enhanced permeability for other topically applied medicinal agents.

CONTRAINDICATIONS

Clindasol-T gel is contraindicated in patients with regional enteritis, ulcerative colitis, or history of antibiotic-associated colitis.

STORAGE & INSTRUCTIONS

Store below 25°C. Do not refrigerate or freeze.

Protect from heat, sunlight and moisture.

Keep away from the reach of the children.

To be sold on the prescription of a registered medical practitioner only.

FOR EXTERNAL USE ONLY.

HOW SUPPLIED

20 g Tube

Manufactured by:

PHARMA SOL

PRIVATE LIMITED

Plot # 549, Sundar Industrial Estate,
Lahore, Pakistan.